Application No.: 10/803,638 Docket No.: TRAUMA 3.0-454

REMARKS

Reconsideration and withdrawal of the rejection of all the claims now in the application (i.e. claims 1-26) is respectfully requested in view of the foregoing amendments and the following remarks.

Initially the Examiner rejected claims 1, 5 and 10 as being anticipated by Bono U.S. Patent 5,954,722. Bono shows a bone plate receiving a part-spherical insert for allowing polyaxial alignment of a bone screw. The plate has openings with spherical inwardly facing surfaces to mate with the partspherical outer surface of the inserts. Applicants have amended claims 1 and 11 to better define the bone plate aperture as well as the insert to distinguish over the surfaces of Bono. example, the amended claim now requires that the outwardly facing recess tapers from the plate upper surface from a first larger cross-section to a second smaller cross-section and from this point the opening in the load bearing element extends on the second smaller diameter to the bone contacting surface parallel to a central axis of the bore. Clearly Bono does not have these now claimed surfaces.

The limitation that the recessed surface arranged around the aperture or the opening in the bone plate tapers inwardly from the upper surface of the load bearing element to side walls forming the aperture is not taught or suggested by Bono.

The Examiner rejects claims 2, 3, 4, 6, 7, 9 and 11-15 as being unpatentable over Bono in view of Haag et al. U.S. Patent 5,976,141. The Examiner considered Bono failed to disclose an insert having the limitations of a resilient extension with a projection in the locking mechanism which interacts in the area of the underside of the load bearing element. The Examiner considered that Haag disclosed a threaded insert for a bone plate which has a locking mechanism with an

extension and projection 22. Applicants have amended claims 1 and 11 to require that the elongate load bearing element such as a bone plate has a recessed outwardly facing surface tapering towards the bone contacting surface from a larger cross-section to a smaller cross-section with sidewalls extending from the smaller cross-section toward the bone contacting surface. The sidewalls either extend in a direction parallel to the central axis of the opening or perpendicular to the bone contacting surface. Such limitations are neither taught nor suggested by a combination of Bono and Haag. Bono has part spherical surfaces and Haag has an angled surface.

New claims 16-26 have been added to further define an invention which claims distinguishes over Bono.

New claims 16 and 26 claim an insert having surfaces that are complimentary to and engage the surfaces of the openings in the plate. Bono teaches an insert having an outer surface that matches the side walls of the openings in the load bearing element or plate. Bono does not have the claimed recessed area at all. The Examiner argues that a recess is defined as an indentation, hollow or alcove. The opening of Bono shows an entry passage having a rounded edge. Afterwards the opening is barrel-shaped which means that the opening of Bono is concave in its cross sectional view.

The opening according to the present patent application neither shows an entry passage having a rounded edge nor a barrel-shaped surface of the opening. New claims 16 and 26 have been drafted in order to be more precise. Thereby the recessed surface is defined as being arranged around the opening and extends and tapers inwardly from an upper surface of said load-bearing element. This is disclosed in paragraph [0025] of the application text as it has been filed and one is also able to recognize such features in the drawings.

It is submitted that the expression "tapers inwardly" is a feature that shows a clear distinction to Bono. Relating to claim 16, "taping outwardly" recites the same feature starting from the perpendicular side walls, another structural feature not being part of Bono.

According to the description, the Bono insert is press-fitted onto the opening (column 4, line 24). The insert then is able to withstand pressure applied on it. However, due to its shape, it may still be possible for the insert to perform a rotational movement within the opening. Bono teaches that the insert may be rotated in the opening in order to adjust the angular direction of the screw to be received by the insert (column 5, lines 7-10). According to the present invention as it is disclosed in paragraph [0037], the opening is arranged angularly and a kit provided for surgery there would comprise a series of different inserts with various angles wherein every insert defines the longitudinal direction of the screw (fixation element) and no insert can change orientation when mounted into the plate.

With regard to Haag, Haag discloses an insert that contacts the surface of the opening of the load bearing element with its edges. Therefore any resulting forces or load will be transferred from the insert to the load bearing element via a contacting area in the shape of a thin line or edge. This will lead to deformation of both the load bearing element and the insert as they are disclosed by Haag. Furthermore, the forces according to the arrangement of Haag are mainly carried by the insert itself rather than by the load bearing element itself.

Whereas Bono teaches an insert having an outer surface that matches an inner surface of an opening in a plate. The resulting forces or load as disclosed by Bono is distributed over the area of the outer surface. A deformation as is the case according to Haag is not possible according to the

technical teaching of Bono. Due to the contacting surface it is clear that the forces are mainly carried by the plate, since the transmission of the forces is more advantageous.

A further difference between Bono and Haag is that the insert according to Bono is being moveable when it is inserted, while the insert according to Haag is being fixed and locked in its position. This means that the locking status from Bono and Haag is different.

According to the arguments brought forward above, namely the difference in the transmission of the load and that status of the insert when it is inserted, the person skilled in the art would not combine the technical teachings according to Bono and technical teaching according to Haag.

Because the inserts of Haag and Bono perform such dissimilar functions with the insert of Haag et al. obviously designed to be stationary there would be no suggestion in either specification for their combination. If some how the locking feature of Haag et al. were combined with Bono et al. Bono inserts would then be unable to rotate. The only locking feature of Bono is the expansion of the insert so that forces between the spherical outer surface of the insert and the spherical inner surface of the aperture of the bone plate allow locking in any position. This would not be the case if the projections 22 of Haag et al. were included in the Bono design. Thus, each reference teaches away from its combination with the other.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he/she telephone applicant's

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attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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Respectfully submitted

Raymond W. Augustin

Registration No.: 28,588 LERNER, DAVID, LITTENBERG,

KRUMHOLZ & MENTLIK, LLP

600 South Avenue West

Westfield, New Jersey 07090

(908) 654-5000

Attorney for Applicants

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